

TENNESSEE GENERAL ASSEMBLY  
FISCAL REVIEW COMMITTEE



**FISCAL NOTE**

**HB 9057**

October 27, 2021

**SUMMARY OF BILL:** Adds treatments for COVID-19 as an “investigational drug, biological product, or device” under the *Phil Timp – Amanda Wilcox Right to Try Act* (Act).

**ESTIMATED FISCAL IMPACT:**

**NOT SIGNIFICANT**

Assumptions:

- Pursuant to Tenn. Code Ann. § 63-6-301 – 309, the Act authorizes an eligible patient to utilize an investigational drug, biological product or device that has completed phase 1 of a clinical trial but has not yet been approved for general use by the federal Food and Drug Administration (FDA) and remains under investigation in a clinical trial that is approved by the FDA. An eligible patient is an individual who has an advanced illness, has considered all other FDA-approved treatment options, has received a recommendation from the patient’s physician for an investigational drug, biological product, or device, has given written, informed consent for the use of an investigational drug, biological product, or device, and has documentation from such physician that the patient meets all the aforementioned requirements.
- The Act does not expand the coverage required of an insurer. A health plan, third-party administrator, or governmental agency is not required to provide coverage for the cost of or services related to the use of an investigational drug, biological product, or device.
- No state or local government health insurance policies or payouts will be impacted by the approval of additional treatments or eligible patients under the Act.
- No significant fiscal impact to state or local government.

**CERTIFICATION:**

The information contained herein is true and correct to the best of my knowledge.

A handwritten signature in black ink that reads "Krista Lee Carsner".

Krista Lee Carsner, Executive Director

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